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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/806,972 | 03/22/2004 | Stephen Donovan | 17500CON (BOT) | 2337 |

7590 02/08/2005

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| EXAMINER | |
|---|---|
| PORTNER, VIRGINIA ALLEN | |
| **ART UNIT** | **PAPER NUMBER** |
| 1645 | |

DATE MAILED: 02/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/806,972 | DONOVAN, STEPHEN | |
| | Examiner | Art Unit | |
| | Ginny Portner | 1645 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *10/25/2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

Claims 1-22 are pending.
Claim 23 has been canceled.
Claims 1, 7, 17, 20 and 21 have been amended.
1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### Rejections/Objections Withdrawn

**2.** Claim 7 objected to because of the following informalities: Claim 7 recites the term "effect"; this term lacks antecedent basis in claim 1 from which it depends which recites the term "symptom", has been obviated in light of the amendment of claim to delete the term "effect".
**1.** Claim 23 provisionally rejected under the judicially created doctrine of double patenting over claims 10-11 of copending Application No. defined by PG-Pub 20040062776, in light of the cancellation of claim 23.
**2.** Claim 23 provisionally rejected under the judicially created doctrine of double patenting over claims 1-5,10-12 of copending Application No. defined by PG-Pub 20040018213, in light of the cancellation of claim 23.
**3.** Claim 23 provisionally rejected under the judicially created doctrine of double patenting over claims 1, 3-4, 10-12 of copending Application No. defined by PG-Pub 20040018212, in light of the cancellation of claim 23.
4.
1. Claims 1-23 rejected under 35 U.S.C. 112, first paragraph (scope), because the specification, while being enabling for a method of alleviating at least one symptom associated with a neuropsychiatric disorder with specific, non-toxic doses of clostridial neurotoxin, delivered locally to the cite which effects the symptom to be alleviated, does not reasonably provide enablement for the administration of any dosage size to any local intracranial location of a mammal in a method of treating any neuropsychiatric disorder. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims, in light of the claims having been amended to recite "non-lethal" and "within the skull of the patient".

**2.** Claims 1-23 rejected under 35 U.S.C. 112, first paragraph (scope), because the specification, while being enabling for a method of alleviating at least one symptom associated with a neuropsychiatric disorder with specific, non-toxic doses of clostridial neurotoxin, delivered locally to the cite which effects the symptom to be alleviated, does not reasonably provide enablement for the administration of any dosage size to any local intracranial location of

a mammal in a method of treating any neuropsychiatric disorder. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims, in light of the claims having been amended to recite "non-lethal" and "within the skull of the patient".

5. Claims 1-5, 7,12-20, 23 rejected under 35 U.S.C. 102(b) as being anticipated by Auchus, A et al (1995), in light of the claims being amended to recite a local site of the skull.

6. Claims 1-4,7,9 and 12 rejected under 35 USC 102(b) as being anticipated by Micheli et al (1998) in light of the amendment of the claims to recite a new combination of claim limitations, specifically skull and intracranial locations.

**Definitions** provided by the instant Specification and Glossary of Skeletal Anatomy for claim limitations used to amend pending claims:

3. All pending claims have been amended to recite the phrase "**locally administered** to neural tissue at **an intracranial site within the skull** of the patient".

The term **"local administration"** is defined in the instant Specification at page 22, lines 8-12, to mean "direct administration of the pharmaceutical at or to the vicinity of a site on or within an animal body at which site a biological effect of the pharmaceutical is desired. Local administration excludes systemic routes of administration such as intravenous and oral administration". Based upon Applicant's definition, the administration need only be in the vicinity of an intracranial site.

The instant Specification (also known as PG-Pub 20040180061 A1, at Page 7, [0076] ) defines "**Intracranial**" means within the cranium or at or near the dorsal end of the spinal cord and includes the medulla, brain stem, pons, cerebellum and cerebrum" . A species of this definition is now recited in the amended claims which is limited to the "skull". The term "skull" is defined to include the cranium and the mandible, but the claims further limit what is

claimed to be directed to an "intracranial" site. The cranium (intracranial) includes "the face and the calvarium", the calvarium being defined to include the brain case (see glossary of skeletal anatomy definition of the term human "skull"). Therefore the administered composition is into or in the vicinity of the face, or brain case of a patient based upon the recitation and combination of terms defined in the instant specification "locally", "intracranial" and the art recognized definition of the term "skull".

All of the claims are directed to a method of alleviating a symptom of a neuropsychiatric disorder. The instant Specification defines the term "neuropsychiatric disorder to include within its meaning (see Page 7 [081] ) : " The neuropsychiatric disorders treated in accordance with the methods disclosed herein include, and **are not limited to**, schizophrenia, Alzheimer's disease, mania, and anxiety. "

Upon consideration of art recognized neuropsychiatric conditions, the examiner found:

4. Thibaut et al (1995, abstract) to define "several neuropsychiatric diseases" to include:

   a. Idiopathic Parkinson's disease

   b. Tourette's disease

   c. Schizophrenia and

   d. Cocaine addition.

5. Shabnam et al (2003, abstract) to define Parkinson's disease to evidence a common neuropsychiatric symptom, specifically depression (see abstract background, first sentence).

6. Lieberman, A (June 1998, complete reference) describes the neuropsychiatric symptoms of Parkinson's disease (see title, abstract and entire document).

7. Fujimori et al (Oct. 2004, abstract) lists neuropsychiatric disorders to include:

e. Epilepsy i. Drug addiction.

f. Depression

g. Schizophrenia

h. Stiff-person syndrome

8. Sacco et al (Dec. 2004, abstract) lists neuropsychiatric disorders to include:

i. ADHD

j. Alzheimer's disease

k. Schizophrenia,

l. Affective disorders

m. Parkinson's disease

n. Tourette's disorder.

9. The term "**a symptom**" recited in the claims is being read to include the definition provided in PG-Pub 20040180061 (published Specification for instant Application):

Page 10, [0105] Significantly, a method within the scope of the present invention can provide improved patient function. "Improved patient function" can be defined as an improvement measured by factors such as a reduced pain, reduced time spent in bed, increased ambulation, healthier attitude, more varied lifestyle and/or healing permitted by normal muscle tone. Improved patient function is synonymous with an improved quality of life (QOL). QOL can be assessed using, for example, the known SF-12 or SF-36 health survey scoring procedures. SF-36 assesses a patient's physical and mental health in the eight domains of physical functioning, role limitations due to physical problems, social functioning, bodily pain, general mental health, role limitations due to emotional problems, vitality, and general health

perceptions. Scores obtained can be compared to published values available for various general and patient populations.

Additionally, the phrase "**a symptom**" is being read to include the definition provided at Page 7, [083] of PG-Pub 20040180061 "Another preferred method within the scope of the present invention is a method for improving patient function, the method comprising the step of intracranially administering a neurotoxin to a patient, thereby improving patient function as determined by improvement in one or more of the factors of reduced pain, reduced time spent in bed, increased ambulation, healthier attitude and a more varied lifestyle.

**Anxiety** is defined to being one of the neuropsychiatric disorders within the scope of what is now claimed. Upon consideration of the definition provide by "Medline Plus", the term "anxiety" was defined in alternative terms to include: stress; tension, jitters, apprehension, feeling uptight, and evidence "symptoms" which include: twitching, trembling, muscle tension, headaches, sweating, dry mouth, difficulty swallowing, and abdominal pain.

**Please Note**: Based upon Applicant's definitions of neuropsychiatric disorders to include Parkinson's disease, Alzheimer's disease, epilepsy and headaches, as well as other neuropsychartic disorder, the following rejections and objections are being maintained.

**Rejections/Objections Maintained**

7. Claims 1-5,7-12,17-18,20 are provisionally rejected under the judicially created doctrine of double patenting over claims 1-3,5-12 of copending Application No. 10/421,504, for reasons of record and in light of the fact that the claims in 10/421,504 are directed to a method of treating epilepsy, a species within the instantly claimed genus.

8. Claims 1-5,7-12, 17-18, 20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 5-13 of U.S. Patent

No. US Pat. 6,620,415, for reasons of record and in light of the fact that the allowed claims are directed to a species of invention, specifically a method of treating Parkinson's disease,

9. Claims 1-5,17-18 and 20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 and 5 of U.S. Patent No. US Pat. 6,372,226, for reasons of record and in light of the fact that the allowed claims are directed to a species of invention, specifically a botulinum toxin, and the allowed claims are directed to a species of the instantly claimed genus directed, specifically a method of alleviating pain through administering the neurotoxin to a specific intracranial site.

10. Claims 1-5,17-18 and 20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 and 13 of U.S. Patent No. US Pat. 6,333,037 for reasons of record and in light of the fact that the allowed claims are directed to a species of invention, specifically a method that administers botulinum toxin to a cranial site (claim 13).

11. Claims 1-5,17-18 and 20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3,5,9-17 and 13 of U.S. Patent No. US Pat. 6,306,403 for reasons of record and in light of the fact that the allowed claims are directed to a species of invention, specifically a method of treating Parkinson's disease through administering the neurotoxin to an intracranial site.

12. Claims 1-5,7-8,10,12-20 rejected under 35 U.S.C. 102(b) as being anticipated by Binder (US Pat. 5,714,468), for reasons of record in light of Applicant's definitions and discussion above.

13. Claims 1-8,10-20 rejected under 35 U.S.C. 102(e) as being anticipated by Aoki et al (US Pat. 6,458,365), ), for reasons of record in light of Applicant's definitions and discussion above.

14. Claims 1-5, 7,17-19, 21-22 rejected under 35 U.S.C. 102(b) as being anticipated by Bassitt et al, for reasons of record and Applicant's definitions of the claimed invention to include improved function (spasms prevented) and improved quality of life.

***Response to Arguments***

15. The rejection of claims 1-5,7-12,17-18,20 provisionally under the judicially created doctrine of double patenting over claims 1-3,5-12 of copending Application No. 10/421,504, is traversed on the grounds that the instant application claims are directed to a genus of methods of treating a neuropsychiatric disorder, and the claims of co-pending application 10/421,504 are directed to a method of treating epilepsy, which is a movement disorder and the symptoms that the methods are seeking to treat are mental faculties, thinking, cognition, mood, social behavior, memory, learning and intelligence.

10. It is the position of the examiner that Applicant's definition of symptoms to be treated include symptoms of movement disorders that are associated with patients that are considered to have a neuropsychiatric disorder (see symptoms definition above). Fujimori et al (Oct. 2004, abstract) lists neuropsychiatric disorders to include Epilepsy and therefore, the pending claims of 10/421,504, directed to a method of treating epilepsy, through intracranially administering botulinum toxin, is a species that anticipates the instantly claimed genus of methods. While it is true that the non-movement associated symptoms find support in the instant Specification, none of the claims recite this combination of symptoms to be treated, wherein the treatment improves the disorder through improved cognition. Applicant's arguments are not commensurate in scope with what is now claimed. The rejection is maintained for reasons of record.

The rejection of claims 1-5,7-12, 17-18, 20 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 5-13 of U.S. Patent No. US Pat. 6,620,415; and

The rejection of claims 1-5,17-18 and 20 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3,5,9-17 and 13 of U.S. Patent No. US Pat. 6,306,403

are traversed on the grounds that Parkinson's is a movement disorder that is not neuropsychiatric disorder recited in the claims and asserts the symptoms being treated are cognition-based symptoms.

11. It is the position of the examiner that while it is true that the non-movement associated symptoms find support in the instant Specification, none of the claims recite this combination of

symptoms to be treated, wherein the treatment improves the disorder through improved cognition. Applicant's arguments are not commensurate in scope with what is now claimed.

Applicant's definition of symptoms to be treated include symptoms of movement disorders that are associated with patients that are considered to have a neuropsychiatric disorder. Shabnam et al, Liberman et al and Sacco et al (references cited above) lists Parkinson's disease to be a neuropsychiatric disorder with neuropsychiatric symptoms. The allowed claims are directed to a species of invention, that anticipates the instantly claimed genus. The rejection is maintained for reasons of record.

16. The rejection of claims 1-5,17-18 and 20 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 and 5 of U.S. Patent No. US Pat. 6,372,226 is traversed on the grounds that a method of treating pain is does not render a method of treating a neuropsychiatric disorder obvious.

It is the position of the examiner, that in light of Applicant's definition, which includes anxiety and the symptoms associated therewith, as well as treating pain (see definitions above), the allowed claims are directed to a species of the instantly claimed genus directed, specifically a method of alleviating pain (Page 7, [083] of PG-Pub 20040180061) through administering the neurotoxin to a specific intracranial site. The allowed species anticipates the instantly claimed genus of methods. The rejection is maintained for reasons of record.

17. The rejection of claims 1-5,17-18 and 20 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 and 13 of U.S. Patent No. US Pat. 6,333,037 is traversed on the grounds that a method of treating pain is not a method

of treating a neuropsychiatric disorder, and the allowed claims do not render obvious the instantly claimed invention.

It is the position of the examiner that the allowed claims are directed to a species of the instantly claimed genus directed, specifically a method of treating pain through administering the neurotoxin to a cranial site (claim 13), wherein Applicant's definition of a neuropsychiatric disorder includes anxiety and the symptoms associated therewith, to include treating pain (see definitions above) associated with the symptoms of the disorder. The allowed claims are directed to a species of the instantly claimed genus directed, specifically a method of alleviating pain (Page 7, [083] of PG-Pub 20040180061) through administering the neurotoxin to a specific intracranial site. The allowed species anticipates the instantly claimed genus of methods. The rejection is maintained for reasons of record.

18. The rejection of claims 1-5,7-8,10,12-20 under 35 U.S.C. 102(b) as being anticipated by Binder (US Pat. 5,714,468), is traversed on the grounds that Binder only administers Clostridial neurotoxin intramuscularly and treat conditions other than neuropsychiatric disorders.

19. It is the position of the examiner that the reference discloses both intramuscular and extramuscular administration of clostridial neurotoxin, extramuscular is a preferred mode of administration (see abstract, to "cranium"; Table 1(a and b (depressive, anxiety states), col. 4, lines 11-12, claims 2, 12 and 21). Additionally, anxiety tension headaches are treated with intracranial administration for treatment of a symptom of a neuropsychiatric disorder; the term used by Binder is " neurological disorders", which is a species of neuropsychiatric disorder (anxiety, recited in Table 1b). While Binder may not mention the term "neural tissue", the

extramuscular administration of clostridial neurotoxin to a nerve junction of the cranium would inherently include neural tissue of the cranium. The administered clostridial neurotoxin produces a "reversible, flaccid paralysis of mammalian skeletal muscle, presumably by blocking the exocytosis of acetylcholine at peripheral, presynaptic cholinergic receptors", and functions at "neuromuscular junctions" (see entire Binder reference). The reference inherently anticipates the instantly claimed invention. See In re Atlas, 1999.

20. The rejection of claims 1-8,10-20 under 35 U.S.C. 102(e) as being anticipated by Aoki et al (US Pat. 6,458,365) is traversed on the ground that Aoki et al disclose the administration of botulinum toxin to the muscles of the head, and claims recite neural tissue.

21. It is the position of the examiner that while the clostridial neurotoxin of Aoki et al is administered to the muscular regions of the head where tension headaches are localized, the , the mode of action of the clostridial neurotoxin is due to the inhibition of neurotransmitter release (see col. 10, claim 8, col. 9, lines 48-53). Aoki et al teach that the clostridial neurotoxin is specific for neuronal tissue (nerve tissue) associated with the muscles of the head by stating: "Botulinum toxins appear to be zinc endopeptidases, the mechanism of action of different serotypes, for example, A and E within the neuron appear to be different than that of Type B. In addition, the neuronal surface "receptor" for the toxin appears to be different for the serotypes."

Inherently the reference anticipates the instantly claimed invention that administers a clostridial neurotoxin to the neuronal tissue for resolution of symptoms associated with anxiety, which includes tension headaches (head pain due to muscle tension in the head (analogous to the term skull). The modes of administration taught by Aoki et al include subcutaneously or intramuscularly, and the instant claims recite intracranially which includes any mode of administration that is local to the face or brain case (see definitions above). The symptom reduced is the headache. See In re Atlas 1999.

22. The rejection of claims 1-5, 7,17-19, 21-22 under 35 U.S.C. 102(b) as being anticipated by Bassitt et al, is traversed on the grounds that the botulinum toxin was administered intramuscularly and the patient was not administered to treat a neuropsychiatric disorder or a symptom thereof as recited in the claims.

23. It is the position of the examiner that the patient of Bassitt et al was a paranoid schizophrenic with secondary Parkinson's disease (see page 155, col. 1, paragraph 2). One of the symptoms the patient developed over the course of the disease was tardive dyskinesia. The symptomatic region of the face, the face being considered part of the cranium, received an intracranial (interfacial, eyelids are apart of the face and were injected), local administration of botulinum toxin. Botulinum toxin acts upon neuronal tissue within the local area to which it is administered and served to alleviate a symptom of the patient with the neuropsychiatric disorder.

The skull comprises the parts of the cranium which includes the brain case and the face. The patient's face (eyelids) were injected with botulinum toxin to alleviate a symptom of the neuropsychiatric disorder. The rejection is maintained for reasons of record and definitions considered from the instant Specification (discussed above).

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***New claim limitations/New Grounds of Rejection/Objection***

***Claim Rejections - 35 USC § 112***

24. Claims 8-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

25. Claims 8-9 recites the limitation "to a lower brain region" and "to a pontine region" in an effort to further limit claim 1, which has been amended to recite the phrase "locally administered to neural tissue at an intracranial site with the skull of the patient". There is insufficient antecedent basis for the claim limitations set forth in claim 8-9 in claim 1, as claims 8-9 define regions that are not local to the brain case and face of the patient that are within the definition of intracranial skull region of newly amended claim 1.

***Claim Objections***

26. Claims 8-9 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 8-9 define a region that is not local to the brain case or face of a patient. Claim 1 has been amended to recite a combination of claim limitations that do not include the lower brain region or pontine region, as claim 1 has been amended to recite local administration to an intracranial site of the skull , which includes the brain case and face. Claims 8-9 broaden the scope of claim 1 and therefore are not further limiting of claim 1.

***Conclusion***

27. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

28.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (703)308-7543. The examiner can normally be reached on Monday through Friday except for the first Friday of each two week period.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for this group is (703) 308-4242.

The Group and/or Art Unit location of your application in the PTO will be Group Art Unit 1645. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to this Art Unit.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vgp
February 1, 2005

LYNETTE R. F. SMITH
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